

We claim:

1. A microparticulate system for drug delivery to the pulmonary system comprising:

synthetic biodegradable microparticles incorporating a therapeutic, prophylactic or diagnostic agent, wherein the microparticles have a diameter between 0.5 microns and ten microns and release the incorporated agent at a pH of 6.0 or greater, in a pharmaceutically acceptable carrier for administration to the lungs.

2. The system of claim 1 wherein the microparticles are made from a material selected from the group consisting of diketopiperazines, poly(hydroxy acids), polyanhydrides, polyesters, polyamides, polycarbonates, polyalkylenes, polyvinyl compounds, polysiloxanes, polymers of acrylic and methacrylic acids, polyurethanes and co-polymers thereof, celluloses, poly(butic acid), poly(valeric acid), poly(lactide-co-caprolactone), polysaccharides, proteins, copolymers and mixtures thereof.

3. The system of claim 2 wherein the material is diketopiperazines.

4. The system of claim 1 wherein the agent is selected from the group consisting of proteins, polysaccharides, lipids, nucleic acids and other biologically active organic molecules, and combinations thereof.

5. The system of claim 4 wherein the agent is selected from the group consisting of insulin, calcitonin, felbamate, heparin, parathyroid hormone and fragments thereof, growth hormone, erythropoietin, AZT, DDI, G CSF, lamotrigine, chorionic gonadotropin releasing factor, luteinizing releasing hormone,

vaccines, gene encoding adenosine deaminase, and Argatroban.

6. The system of claim 1 wherein the microparticles are a dry powder provided with an apparatus for administration of the microparticles to the lungs.

7. A method for drug delivery to the pulmonary system comprising:

administering to a patient in need of treatment an effective amount of synthetic biodegradable microparticles incorporating a therapeutic, prophylactic or diagnostic agent, wherein the microparticles have a diameter between 0.5 microns and ten microns and release the incorporated agent at a pH of 6.0 or greater, in a pharmaceutically acceptable carrier for administration to the lungs.

8. The method of claim 7 wherein the material is selected from the group consisting of diketopiperazines, poly(hydroxy acids), polyanhydrides, polyesters, polyamides, polycarbonates, polyalkylenes, polyvinyl compounds, polysiloxanes, polymers of acrylic and methacrylic acids, polyurethanes and co-polymers thereof, celluloses, poly(butic acid), poly(valeric acid), poly(lactide-co-caprolactone), polysaccharides, proteins, copolymers and mixtures thereof.

9. The method of claim 8 wherein the material is diketopiperazines.

10. The method of claim 7 wherein the agent is selected from the group consisting of proteins, polysaccharides, lipids, nucleic acids and other biologically active organic molecules, and combinations thereof.

11. The method of claim 10 wherein the agent is selected from the group consisting of

insulin, calcitonin, felbamate, heparin, parathyroid hormone and fragments thereof, growth hormone, erythropoietin, AZT, DDI, G CSF, lamotrigine, chorionic gonadotropin releasing factor, luteinizing releasing hormone,  $\beta$ -galactosidase and Argatroban.

12. The method of claim 7 wherein the microparticles are a dry powder provided with an apparatus for administration of the microparticles to the lungs.

13. An apparatus for administration of a powder or microparticles to the pulmonary tract comprising

a reservoir for administration of the powder or microparticles,

a reservoir for compressed air,

a pump to compress the air in the air reservoir,

a breath activatable valve between the powder reservoir and an opening insertable into the mouth of a patient in need of treatment with the powder or microparticles, and

a means for inserting the powder or microparticles into the powder reservoir.

14. The apparatus of claim 13 wherein the means for inserting the powder is a rupturable device containing the powder in combination with a means for rupturing the device.

15. The apparatus of claim 14 wherein the device is a capsule and the means for rupturing the capsule is a plunger.